12-0900-10664-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed
Permanent Rules Governing
Health Maintenance Organizations,
Minnesota Rule 4685.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Steve M. Mihalchick on August 3, 1998, at 9:00 a.m. in Room 300N of the State Office Building, 100 Constitution Avenue, Saint Paul, Minnesota.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. §§ 14.131 to 14.20, to hear public comment, to determine whether the Minnesota Department of Health (Department) has fulfilled all relevant substantive and procedural requirements of law applicable to the adoption of the rules, whether the proposed rules are needed and reasonable and whether or not modifications to the rules proposed by the Department after initial publication are impermissible substantial changes.

Audrey Kaiser Manka, Assistant Attorney General, 525 Park Street, St. Paul, Minnesota 55155, appeared on behalf of the Department. The Department's hearing panel consisted of Susan Margot, Rule Writer; Irene Goldman, Staff Attorney; and Kent Peterson, Health Program Manager.

Approximately thirty persons attended the hearing. Twenty-four persons signed the hearing register. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the adoption of these rules.

The record remained open for the submission of written comments for twenty calendar days following the date of the hearing, to August 24, 1998. Pursuant to Minn. Stat. § 14.15, subd. 1 (1996), five working days were allowed for the filing of responsive comments. At the close of business on August 31, 1998, the rulemaking record closed for all purposes. The Administrative Law Judge received twenty-three written comments from interested persons during the comment period. The Department submitted written comment responding to matters discussed at the hearings and making changes in the proposed rules.

This Report must be available for review to all interested persons upon request for at least five working days before the Department takes any further action on the proposed amendments. The Department may then adopt a final rule, or modify or withdraw its proposed amendments.

Pursuant to the provisions of Minn. Stat. § 14.15, subd. 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse Findings of this Report, he will advise the Department of actions which will correct the defects and the Department may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected.

If the Department elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the Department may proceed to adopt the rule and submit it to the Revisor of Statutes for a review of the form. If the Department makes changes in the rule other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, then it shall submit the rule, with the complete record, to the Chief Administrative Law Judge for a review of the changes before adopting it and submitting it to the Revisor of Statutes.

When the Department files the rule with the Secretary of State, it shall give notice on the day of filing to all persons who requested that they be informed of the filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Procedural Requirements

1. The Department filed the following documents with the Administrative Law Judge at the hearing:

a) the Department's Request for Comments published at 21 State Register 175 (Exhibit 1A);

b) a copy of the proposed rules certified by the Revisor of Statutes (Exhibit 1C);

c) the Statement of Need and Reasonableness (SONAR) (Exhibit 1D);

d) copies of the transmittal letter and certificate of mailing the SONAR to the Legislative Reference Library (Exhibit 1E);

e) the dual Notice of Hearing as mailed and published at 22 State Register 2280 (Exhibit 1F);

f) the certification of the Department's mailing list as accurate and correct, a copy of the list, and certification of mailing to that list (Exhibit 1G);

g) the letter from the Administrative Law Judge approving the Department's Notice Plan and the Department's certifications of publication and mailing notice according to that plan (Exhibit 1H);

h) all materials received in response the published Notice of Hearing (Exhibit 1I-1 through I-79).

i) modifications of the proposed rule after publication in the State Register (Exhibit 1K);

j) a Summary of Proposed Amendments, explaining the reasons for the modifications to the proposed rule (Exhibit 1L); and

k) a copy of the notice provided to those persons who requested a hearing in this matter and the certification of mailing that notice (Exhibit 1M).

2. On June 3, 1998, the Department requested approval of an additional notice plan that included direct mailing of a notice to HMOs, CISNs, providers, plan enrollees, vendors, trade groups to the various health professions, organizations that represent plan enrollees, and organizations representing purchasers of HMO products. The additional notice plan was approved on June 8, 1998.[1]

3. On June 16, 1998, the Department mailed the Notice of Hearing to all persons and associations who had registered their names with the Department for the purpose of receiving such notice.[2]

4. On June 22, 1998, the Department published a copy of the proposed rules and the Notice of Hearing at 22 State Register 2280.[3]

Statutory Authority.

5. In its Notice of Hearing, the Department cites Minn. Stat. § 62D.20 as its statutory authority to adopt the proposed rules. The statute 144.11 states, in relevant part:

> Subdivision 1. Rulemaking. The commissioner of health may, pursuant to chapter 14, promulgate such reasonable rules as are necessary or proper to carry out the provisions of sections 62D.01 to 62D.30. Included among such rules shall be those which provide minimum requirements for the provision of comprehensive health maintenance services, as defined in section 62D.02, subdivision 7, and reasonable exclusions therefrom. . . .
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> Subd. 2. Prior authorization. The commissioner shall adopt rules that address the issue of appropriate prior authorization requirements, considering enrollee needs, administrative concerns, and the nature of the benefit.

6. Minn. Stat. ch. 62N governs Community Integrated Service Networks (CISNs). Minn. Stat. § 62N.25, subd. 3, applies the rules and statutes (except as otherwise stated) governing HMOs to CISNs.

7. The Commissioner is expressly authorized to adopt rules governing HMOs. By operation of statute, those rules also govern CISNs. The Administrative Law Judge concludes that the Department has the statutory authority to promulgate these rules.

Nature of the Proposed Rules.

8. Health care services are obtained by many people through Health Maintenance Organizations (HMOs). HMOs are organized around the principle that the cost of health care can be reduced by standardizing services provided and obtaining economies of scale. By the Department's estimate, thirty percent of Minnesotans (approximately 1.4 million people) are enrolled in HMOs in the state.[4] Due to changes in the manner HMOs are providing health care coverage and statutory changes, the Department perceived a need to modify its rules in this area.[5]

9. The proposed rules add and modify definitions, amend the scope of the rules to cover CISNs, expressly include mental health and chemical dependency care, create separate lists of permissible limitations and permissible exclusions of items of care, and establish standards for HMO pharmaceutical formularies. The availability and accessibility standards are amended to expressly state referral procedures. Quality assurance rule requirements are amended to add requirements for accepting and evaluating complaints. This Report will reference HMOs as the regulated industry unless a reference to CISNs is needed for purposes of clarity.

Cost and Alternative Assessments in SONAR.

10. Minn. Stat. § 14.131 provides that state agencies proposing rules must identify classes of persons affected by the rule, including those incurring costs and those reaping benefits; the probable effect upon state agencies and state revenues; whether less costly or less intrusive means exist for achieving the rule's goals; what alternatives were considered and the reasons why any such alternatives were not chosen; the costs that will be incurred complying with the rule; and differences between the proposed rules and existing federal regulations.

11. The Department concluded that the rules will result in insignificant costs to the Department and no costs to any other agency.[6] The persons or groups that the Department concludes will be most affected by the rules are HMOs and CISNs, their enrollees, their providers, and persons and organizations who purchase HMO and CISN plan coverage.[7]

12. The Department's analysis suggests that most affected groups will be affected in both positive and negative ways by the proposed rules. Enrollees and purchasers will experience increased premiums arising from any increase in plan costs being passed on. Those same groups will benefit from improved consumer protections and the efficiencies in administration fostered by the rules. Any costs not passed on will be borne by the HMOs and CISNs.[8] The only groups identified with solely positive impacts were mental health providers and providers whose services are used by referral. The Department believes that these two groups will benefit from the greater clarity provided by the rules.

13. The Department estimated the probable costs of compliance with the proposed rules to include "notification and training of [HMO] staff and providers, computer programming, amendments to evidences of coverage, additional documents and mailings to enrollees."[9] In response to the Department's request for estimates, HMOs submitted estimates of costs to comply ranging from zero to "very large sums."[10] The Department noted that many of the HMOs that would incur costs would have substantial control over those costs and that many are normal costs of doing business.[11] Based on its analysis, the Department concluded that the costs to HMOs and CISNs would be insignificant.

14. The Department considered a number of alternatives in each substantive portion of the rule. As a general matter, the Department considered a prescriptive credentialing program for HMOs as an alternative. Such a program would impose a significant administrative burden and significant costs on each HMO. The Department asserts that each HMO's motivation to reduce risk in providing care and improve administrative efficiency work as effective substitutes for a credentialing program. The Department has met the requirement to consider alternatives to the rules as proposed.

15. Any agency adopting rules must assess all differences between the proposed rule and existing federal regulations. The Department has indicated that there are no requirements in the rules in conflict with Federal standards.

16. A new statutory provision requires agencies proposing rules after August 1, 1998, to consider and implement "rules and regulatory programs that emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals."[12] The Department considered the "most cost effective, least burdensome approach" for quality assurance reporting to be a general standard.[13] The Department concluded that the HMOs would provide appropriate information without prescribing specific information in the proposed rule. Similarly, the Department chose the general standard of "accepted community standards" for HMO policies and procedures rather than a burdensome credentialing program.[14] Where the Department perceived an enduring problem, such as providing referral information to enrollees, detailed rules have been proposed.[15] The Department's approach is consistent with the legislative directive promoting superior achievement through flexibility, where possible.

Effect on Farming Operations.

17. Minn. Stat. § 14.111 (1996), imposes an additional notice requirement when rules are proposed that affect farming operations. The proposed rules will not affect farming operations and the additional notice requirement does not apply.

Standards for Analyzing the Proposed Rule.

18. In a rulemaking proceeding, an administrative law judge must determine whether the agency has established the need for and reasonableness of the proposed rule by an affirmative presentation of facts.[16] An agency need not always support a rule with adjudicative or trial-type facts. It may rely on what are called “legislative facts” — that is, general facts concerning questions of law, policy, and discretion. The agency may also rely on interpretations of statutes and on stated policy preferences.[17] Here, the Department prepared a SONAR setting out a number of facts, statutory interpretations, and policy preferences to support the proposed rules. It also supplemented information in the SONAR with information presented both at the hearing and in written comments and responses placed in the record after the hearing.

19. Inquiry into whether a rule is reasonable focuses on whether the rulemaking record establishes that it has a rational basis, as opposed to being arbitrary. Minnesota law equates an unreasonable rule with an arbitrary rule.[18] Agency action is arbitrary or unreasonable when it takes place without considering surrounding facts and circumstances or disregards them.[19] On the other hand, a rule is generally considered reasonable if it is rationally related to the end the governing statute seeks to achieve.[20]

20. The Minnesota Supreme Court has defined an agency's burden in adopting rules as having to "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."[21] An agency is entitled to make choices between different approaches as long as its choice is rational. Generally, it is not proper for an administrative law judge to determine which policy alternative might present the "best" approach, since making a judgment like that invades the policy-

making discretion of the agency. Rather, the question for an administrative law judge is whether the agency's choice is one that a rational person could have made.[22]

21. In addition to ascertaining whether proposed rules are necessary and reasonable, an administrative law judge must make other decisions — namely, whether the agency complied with the rule adoption procedure; whether the rule grants undue discretion to the agency; whether the agency has statutory authority to adopt the rule; whether the rule is unconstitutional or illegal; whether the rule constitutes an undue delegation of authority to another; and whether the proposed language is not a rule.[23] The SONAR contains information establishing the need for and reasonableness of most of the proposed rules, and the Department's compliance with laws governing the rulemaking process is apparent in most cases. Moreover, a majority of provisions drew no unfavorable public comment. For these reasons, the Administrative Law Judge will not discuss every part and subpart of the proposed rules in this report. Rather, he finds that the Department has demonstrated the need for and reasonableness of all rule provisions not specifically discussed in this report. He also finds that all provisions not specifically discussed are authorized by statute and that there are no other problems that would prevent their adoption.

Standard for Analyzing Proposed Modifications

22. When an agency makes changes to proposed rules after it publishes them in the *State Register*, an administrative law judge must determine if the new language is substantially different from what the agency originally proposed.[24] The legislature has established standards for determining if the new language is substantially different.[25]

Proposed Rule 4685.0100 - Definitions.

23. A number of terms used in the rules are defined in Minn. Rule part 4685.0100. In this proceeding, the definitions of some terms are amended and some new definitions are added. Only the terms generating comments or otherwise needing discussion will be individually mentioned. The remaining definitions are found to be needed and reasonable.

24. Subpart 5 defines "comprehensive health maintenance service" and includes a number of specific subsidiary classes of health care services. Item D further defines "outpatient health services" to include "therapeutic services for congenital, developmental, or medical conditions that have significantly delayed speech or motor development . . . . " Anne Henry of the Minnesota Disability Law Center (MDLC) and Paulette J. Olsen, President of the Minnesota Chapter of the American Physical Therapy Association (MnAPTA), expressed general support of the language in item D, except for the word "significantly."[26] MnAPTA indicated that many denials of therapeutic treatment to children occur because of HMO limitations of coverage and that without some standards as to what constitutes significance, unwarranted denials of care will occur.[27] Edward R. Skarnulis, Ph.D., Chair of the Minnesota Governor's Council on

Developmental Disabilities (MGCDD), indicated that "significantly" will cause confusion and could cause denial of necessary therapies.[28]

25. Michael Scandrett, Executive Director of the Minnesota Council of Health Plans (the Council), objected to the removal of "significantly" from item D. The Council maintained the term aids in applying reasonable limitations on provision of services, since many children are, at one time or another, "technically delayed."[29] Deleting "significantly", the Council argued, would constitute a substantially different rule from the rule as published.[30] The Council also argued for the inclusion of language to allow limiting developmental therapy to children for a reasonable time while progressing toward goals set by the treating physician. The Council did not render an opinion as to whether its suggested language would constitute a substantially different rule.

26. MDLC and Rachel Wobschall, Executive Director, and Ronna Linroth, Funding and Policy Specialist, for a System of Technology to Achieve Results (STAR), objected to the Council's proposed changes. MDLC, MnAPTA, and STAR maintain that the standards of the therapist-physician relationship are already established, functional goals are not always the intended result of therapy, and the language suggested by the Council adds ambiguity.[31] Anita Boucher, Public Policy Director of Courage Center (Courage Center) pointed out that HMOs have a number of evaluations available to limit therapy and HMOs currently set goals for continued provision of services.[32] Cindy Toppin of the St. Paul Rehabilitation Center indicated that current practice limits eligibility for developmental therapy to children falling 1.5 standard deviations below the developmental mean.[33] The commentator questioned whether "significantly" could mean 3.0 standard deviations, which would exclude most children from eligibility.[34]

27. The Department considered the comments regarding the language in item D and concluded that "significantly" does not add to an understanding of the rule's intent. HMOs are only required to provide developmental services when delays fall outside the range of normal.[35] Therefore, the Department deleted "significantly" from item D. The Department declined to add the limiting language suggested by the Council, noting that judgment of health care professionals was that appropriate basis for such limitations.[36] The definition language is needed and reasonable as modified. The modified language clarifies the rule and does not constitute substantially different language from that proposed in the *State Register*.

28. Subpart 5a defines “cosmetic services” for the purposes of this rule. Such services require a definition because they are not covered by HMOs. As originally proposed, the definition included “nonreconstructive surgery and other procedures” that are performed primarily to enhance the patient’s appearance, rather than changing a physiological function. The Council indicated “some cosmetic services that alter an enrollee’s physical appearance without correcting or improving a physiological function may also be reconstructive.[37] Under Minn. Stat. § 62A.25, reconstructive surgery must be covered. The Department deleted the reference to “nonreconstructive” and changed “procedures” to “services” to clarify what falls within the definition. The proposed rule, as modified, is needed and reasonable and not substantially different from the rule as published in the *State Register*.

29. The Department perceived a need to define “custodial care”, insofar as such care is commonly excluded from coverage by HMOs. Subpart 5b is a definition of the term that distinguishes services in meeting many basic activities of daily living (*e.g*. bathing, dressing, walking) from activities requiring a health care professional. The proposed definition is needed and reasonable.

30. Experimental drugs, devices, treatments, and services are commonly excluded from coverage by HMOs. To clarify what falls under these exclusions, the Department proposed a definition of "experimental, investigative or unproven" in subpart 6a. The rule defines the term to mean drugs, devices, treatments, and services that lack reliable evidence concerning their "effect on health outcomes." Jeff Reed, Associate Counsel for HealthPartners, urged that "scientifically based" be used in place of "reliable" when describing evidence about the particular drug, device, treatment, or service that is to be assessed.[38] HealthPartners also suggested expressly placing the decision with the HMO and adding safety and effectiveness as criteria. The Department added "safety" and "effectiveness" to the definition to ensure that the full range of issues that determine whether a drug, device, treatment, or service is experimental, investigative, or unproven. The Department declined to change the required level of evidence from "reliable", due to the possibility of an HMO requiring an "unnecessarily high standard of proof."[39] Requiring reliable evidence in determining whether a particular drug, device, treatment, or service is experimental is not a defect in the proposed rule. The rule as modified is needed and reasonable. The new language is not substantially different from the rule as published in the *State Register*.

Proposed Rule 4685.0700 - Comprehensive Health Maintenance Services.

31. The minimum services that an HMO must provide are set out in proposed rule 4685.0700, subp. 2. The only change proposed by the Department to that subpart is the inclusion of mental health and chemical dependency services on both an inpatient and outpatient basis. The Department explained that the rule language was proposed to bring the rule into compliance with the mental health parity law, Minn. Stat. § 62Q.47.[40] This act was passed in 1995 and prohibits health plans from placing greater financial burdens on enrollees or more limitations on service for mental health and chemical dependency services, compared to medical services.[41] In conjunction with proposing this rule language, the Department is deleting existing rules that conflict with that law.[42] The proposed amendments to subpart 2 are needed and reasonable.

32. Subpart 3 of the existing rule 4685.0700, sets out the combined list of services that could be limited or excluded by an HMO. The Department concluded that the rule would be more readily understood by eliminating the ambiguity inherent in referring to the same services as subject to limitation or exclusion in the same sentence. Proposed subpart 3 sets out the list of health services that may be limited by an HMO. The subpart also clarifies that any health service listed as a permissible exclusion may be included by the HMO as a health service that is limited. The list of permissible exclusions is contained in subpart 4.

33. Item A of subpart 3 allows limitation of outpatient prescription drug benefits to a formulary maintained by the HMO. A formulary is the current list of drugs for outpatient treatment. Item A requires periodic review of the formulary for safety and effectiveness of the drugs listed. The item also sets out the minimum requirements for what drugs must be made available through the formulary. Consistent with the rule standard that the formulary be updated periodically, there is no prescriptive list of drugs that must be included. Rather, all drugs must be included that are needed to provide medically necessary care. As originally proposed, the rule exempted drugs that must be carefully monitored from the formulary limitation. Drugs falling under this practice are described as having a "narrow therapeutic index" (NTI). The Department notes that over 95% of managed care plans use formularies to limit the drugs that may be prescribed.[43]

34. The Department has received complaints from enrollees regarding the limitations on covered drugs arising from use of formularies by HMOs.[44] In response to these complaints, the Department proposed exceptions to the exclusion of some drugs from formulary limitation as consumer protections.[45] The Department originally proposed exceptions for those circumstances when the formulary contains no "safe and effective" drug for the enrollee's condition and those instances where a drug has an NTI, including those drugs on the list maintained under Minn. Stat. § 151.21, subd. 8.

35. Kathleen D. Jaeger, Counsel for the National Pharmaceutical Alliance (the Alliance), which represents manufacturers of generic equivalents, objected to the NTI exception from substitution. The Alliance maintained that the U.S. Food and Drug Administration (FDA) has not accepted the distinction of NTI in developing its equivalency lists.[46]

36. The NTI provision referenced the list of drugs contained in Minn. Stat. § 151.21l, subd. 8. HealthPartners objected to the inclusion of the list as going beyond the Department's statutory authority.[47] HealthPartners recommended deleting the entire provision. The Department concluded that the concept of "narrow therapeutic index" was insufficiently developed for use as a rule standard and deleted the term from the proposed rule. The deletion of narrow therapeutic index from the rule is needed and reasonable. The provision deleted also deleted the reference to Minn. Stat. § 151.21, subd. 8, so no further analysis of the issue is required.

37. HMOs use formularies to reduce the cost of prescription drugs.[48] Costs are often significantly reduced by the selection of lower cost equivalent "generic" drugs to more expensive "branded" drugs. The Department maintains that the rule is concerned only with benefit limitations, not demonstrating a preference between branded or generic drugs.[49] MGCDD expressed concern that the rule lacked standards to ensure that "enrollees whose physician has determined that a particular drug should not be tried because of possible problems, should be protected and allowed to use a drug outside the approved list of HMO formulary drugs."[50] Randy Morris, McGrann, Shea, Franzen, Carnival, Straughn & Lamb, Chartered, on behalf of DuPont Pharmaceuticals (DuPont) quoted the FDA's "Orange Book" [Approved Drug Products with Therapeutic

Evaluations (18th ed. 1998)] on the need for physician control of generic substitution as follows:

> FDA evaluation of therapeutic equivalence in no way relieves practitioners of their professional responsibilities in prescribing and dispensing such products with due care and with appropriate information to individual patients. In those circumstances where the characteristics of a specific product, other than its active ingredient, are important in the therapy of a particular patient, the physician's specification of that product is appropriate.
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> There are some general principles that may affect the substitution of pharmaceutically equivalent products in specific cases. Prescribers and dispensers of drugs should be alert to those principles so as to deal appropriately with situations that require professional judgement and discretion.[51]

38. When an HMO exercises its discretion to limit covered drugs, some drugs prescribed by providers are not available to enrollees without the enrollee paying for the full price of the prescription. There is no difference in impact on the enrollee whether the excluded drug is branded or generic. The enrollee is denied coverage for a medication that a provider has determined to be needed. The Department recognized that excluding coverage for many medications is inconsistent with the first requirement for the contents of a formulary, that it contain "all prescription drugs necessary to provide medically necessary care."[52]

39. To ensure that each formulary meets the requirement to provide "medically necessary care", the Department has proposed a modification to subpart 3.A(3) to require an HMO to "promptly grant an exception to the formulary when the formulary drug causes an adverse reaction, is contraindicated, or is not effective for the enrollee . . . ." The first two conditions are needed and reasonable to ensure that enrollees receive medically necessary care. The meaning of the third condition, when the formulary drug is "not effective for the enrollee", is not clearly stated in the rule language. The rule language could be read to cover a wide spectrum of diverse situations. The most restrictive reading of the language would extend to when no ameliorative effect is obtained from the formulary drug. Under such a reading, an enrollee could be prescribed an effective drug for a condition, but be offered an alternative drug from the formulary that would inadequately address the enrollee's condition. The alternative drug, while inadequate, would be addressing some of the enrollee's medical condition and thereby be considered "effective." Since the copayment provisions only apply when an exemption is granted from the formulary, the enrollee would have to pay the full cost of the prescribed medication, or accept the substitution from the formulary.

40. At the other end of the spectrum, the least restrictive reading of the rule language would require an exemption be granted when any difference in outcome (including the enrollee's perception of a difference between the branded and generic versions of a drug) is obtained. This is a purely subjective standard and would act to significantly undermine the cost savings arising from the use of a formulary. In between the two extremes are situations where the enrollee is receiving some significant benefit from the formulary drug, but another drug not on the formulary might be more effective. This situation was referred to by MDLC and Joanne B. Rogin, M.D., Chair of the Professional Advisory Board of the Epilepsy Foundation of Minnesota, when describing the seizure control problems experienced by enrollees when substitutions were made to prescribed medications.[53] More generally, Patricia L. Franklin of the Minnesota Medical Association (MMA) indicated that "there are times when certain medications are not **as effective** for the patients' particular health condition . . . ."[54] The Department has not described which of these situations would meet the standard being promulgated in this rule. The wide variation between these situations and their disparate impact on enrollees compels the conclusion that this rule language is too vague and this vagueness constitutes a defect in the proposed rule.

41. To cure the vagueness defect in the proposed rule, the Department must adopt language that articulates clear standards as to when an HMO must grant an exemption to the formulary for purposes of covering outpatient drug costs. The MMA and the Minnesota Hospital and Healthcare Partnership suggested adding language that would allow the opinion of the prescribing physician to control the exemption process.[55] The Department expressly declined to place that authority with prescribers.[56] While the Department appropriately assigns the HMOs the task of cost control, the HMOs cannot substitute for the professional judgment of the prescriber. The contraindication and adverse reaction standards are both situations where the prescriber exercises professional judgment to meet clear standards. For the third standard, the Administrative Law Judge suggests as possible curative language the following:

> (3) A health maintenance organization shall promptly grant an exception to the formulary when the formulary drug causes an adverse reaction, when the formulary drug is contraindicated, or when the prescriber determines that a medication must be dispensed as written to provide maximum medical benefit to the enrollee.

42. The suggested language, or something similar to it, would provide a clearer standard for HMOs as to when an exception request must be granted. The standard is consistent with the Department's stated goals for including an exemption process to the formulary, including the "benefit available to those patients for whom it is medically necessary to be maintained on a particular drug."[57] The HMO would be entitled, under this language, to require prescribers to state the reason for the "dispense as written" instruction as part of the exemption process and to deny the exemption when the reason is insubstantial. The suggested language is needed and reasonable to address the legitimate concerns of HMOs, prescribers, and enrollees. Any language that

provides an appropriate standard would not be substantially different from the rule as published in the *State Register*.

43. The imposition of a requirement that HMOs develop and disseminate procedures for obtaining approval of an exception request is needed and reasonable. Bill Conley noted that it is prescribers who are in a position to request an exemption, not enrollees. Adding a reference to the prescriber as a person who must be informed of the exemption process does not constitute substantially different language.

44. The proposed language on enrollee charges (commonly know as copayments) was changed significantly after publication in the *State Register.* The language was changed from discretionary (may) to prescriptive (shall not). The Department stated its intention as follows:

> The rule as proposed provides the opportunity for HMOs to impose a higher flat fee or percentage based copayment than the rate approved by the commissioner for formulary drugs. The HMO may seek a different rate from the commissioner or require a copayment based upon a percentage of the provider's charge instead of the usual flat fee copayment. The department wishes to clarify that HMOs may charge a copayment for a drug provided through the exception process and the copayment may be different than the charge for formulary drugs, but it may not exceed the copayment rates approved under Minnesota Rules, part 4685.0801. Therefore, the department is making a technical modification to cross reference and clarify the rule part establishing the maximum permissible copayments.[58]

45. As finally proposed by the Department, the copayment language states "When a health maintenance organization grants an exception to the formulary, it shall not charge the enrollee more than the approved flat fee copayment or a copayment not to exceed 25 percent of the provider's charge, in accordance with part 4685.0801." This language prohibits charging more than either of two amounts. Without clarification, the implied limit is whichever of the two calculations is lower. The rule language is contrary to the outcome intended by the Department. This is unreasonable and a defect in the proposed rule.

46. To accomplish the end sought by the Department, and thereby cure the defect in the rule, different language must be adopted. The Administrative Law Judge suggests the following:

> When a health maintenance organization grants an exception to the formulary, it shall not charge the enrollee more than the greater of the approved flat fee copayment for formulary drugs or a copayment for the excepted drug not to exceed 25 percent of the provider's charge, in accordance with part 4685.0801.

The suggested language is needed and reasonable to accomplish the Department's goal and is not substantially different from the rules as published in the *State Register*.

47. Minn. Rule 4685.1115, subp. 2.A(10) identifies "durable medical equipment, as applicable" as a service that is a component of an HMO. As originally proposed, durable medical equipment was listed in proposed rule 4685.0700, subpart 4, which lists permissible exclusions from coverage. The original purpose of the rule proposal was to replace the outdated reference to "limitations upon and/or exclusions of the provision of corrective appliances and artificial aids."[59] Prior to the hearing, the Department received a number of comments objecting to the listing of durable medical equipment (DME) as a permissible exclusion. The commentators noted that HMOs all covered DME and that excluding DME would be a substantive change in coverage from that currently offered by HMOs. The Council had maintained that HMOs were required to cover DME by Minn. Stat. § 62E.[60] The Department reconsidered the issue and, prior to the hearing, proposed to move DME from permissible exclusions (subpart 4) to permissible limitations (subpart 3).[61]

48. The Council objected to this change to the rule as proposed. The Council asserts that placing DME in the permissible limitation category constitutes a substantial change in the rule, requiring the Department to initiate a new rulemaking to adopt this language.[62] The Council asserts that an HMO's right to exclude DME from coverage is reflected by the language in Laws of Minnesota 1998, Chap. 334 (codified at Minn. Stat. § 62Q.66). In addition, the Council urged modifying the initial limitation and exclusion language to nonspecific lists (e.g. "Permissible limitations may include:).[63]

49. The language in Minn. Stat. § 62Q.66 does not expressly create any right on the part of HMOs to exclude DME from coverage. The language used in the statute merely reflects the state of the existing rule that combines limitation and exclusion in the same sentence. There is nothing in the language indicating any intent by the Legislature that HMOs begin excluding DME from coverage. The substance of the statute requires HMOs that do cover DME (which are all HMOs in Minnesota) to make available to enrollees the criteria used in making coverage decisions. The statutory language is consistent with the rule provision making DME subject to permissible limitation by HMOs.

50. Legislation that expresses an intent to have HMOs cover DME can be found at Minn. Stat. § 62E. STAR related the Council's own recent interpretation of that statute as requiring HMOs to provide DME "when deemed medically necessary."[64] The statute sets out the standards for "qualified plans" and requires a number three qualified plan to cover "rental or purchase, as appropriate, of durable medical equipment other than eyeglasses and hearing aids."[65] Subdivision 4 of that statute states, "A health maintenance organization which provides the services required by chapter 62D shall be deemed to be providing a number three qualified plan."[66]

51. MnAPTA described DME as "integral components of physical therapy and the therapeutic process" and supported the change of DME to the permissible limitation category.[67] MGCDD indicated that the only devices currently excluded by HMOs were

personal convenience devices.[68] Courage Center and MDLC maintained that DME belongs in the permissible limitation category, but more standards should be included to provide guidance as to what DME is covered.[69] Judy Miller, Manager of Rehabilitation Therapies for Gillette Children's Specialty Healthcare, also urged that standards be adopted to "assure that patients are allowed access to these items for medical reasons."[70]

52. The language of proposed subpart 3 expressly allows HMOs to treat as permissible limitations any item listed in permissible exclusions. The Department relies upon the codification of existing practice to support the inclusion of DME in the limitation category. At present, there are no HMOs that exclude DME from coverage.[71] Every HMO has limits as to what DME is covered.[72] To conclude that permissible exclusion of DME is the current situation would require the HMOs to be operating under the proposed rules (exclusions may be treated as limitations), not the existing rules (limitations upon and/or exclusions of). The Council's argument on the appropriate category for DME is somewhat self-contradictory, since the Council maintains that it "is confident that the industry would **continue the current practice of coverage for DME with reasonable limitations**."[73] The proposed rule, as modified, provides complete confidence that HMOs will cover DME with reasonable limitations. Placing DME in the permissible limitation category will not require HMO coverage of personal convenience devices since those devices do not meet the definition of "health services."[74] The Department's proposed modification reflects the actual practice of HMOs and is both needed and reasonable. While the Department has not proposed any additional standards for the provision of DME, the record in this rulemaking does not demonstrate that the absence of such standards constitutes a defect in the rule as finally proposed.

53. An agency otherwise able to adopt a rule cannot do so if it makes changes to the rule that render the rule "substantially different."[75] The Administrative Procedures Act sets out the analysis to be performed to when a rule is modified as follows:

> (c) In determining whether the notice of intent to adopt or notice of hearing provided fair warning that the outcome of that rulemaking proceeding could be the rule in question the following factors must be considered:
>
> (1) the extent to which persons who will be affected by the rule should have understood that the rulemaking proceeding on which it is based could affect their interests;
>
> (2) the extent to which the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the notice of intent to adopt or notice of hearing; and
>
> (3) the extent to which the effects of the rule differ from the effects of the proposed rule contained in the notice of intent to adopt or notice of hearing. [76]

54. There are no issues raised regarding the first two factors. The HMOs were aware that this rulemaking affects their interests. The subject matter of the rule as published included the extent of DME coverage and that is the subject matter of the rule modification. The Council argues that the extent of the different effect of the proposed modification does not comply with the third factor in that inadequate fair warning as to the impact of the rule change was provided to affected parties (here HMOs).

55. The change proposed here moves the reference to DME from one category permissible exclusion, to the adjacent category, permissible limitations. As discussed in the foregoing findings, the modification conforms the proposed rule language to the current practice in DME coverage afforded by HMOs, and the current statutory standard for qualified plans. The proposed modification occurred prior to the hearing in this matter and all affected persons had ample opportunity to comment on the modification. The extent of the rule change here is rather modest in effect, as modifications in rulemaking proceedings go. To find this modification to be a substantially different rule would undermine one of the reasons for having public hearings on rules and requesting comment from interested persons. That reason is to encourage agencies to listen to public comment, consider it, and act on it when appropriate. The rule as modified is not substantially different from the rule as published in the *State Register*.

56. In addition to DME, commentators objected to the permissible exclusion of home health care.[77] The Department agreed with the comments and moved home health care from the permissible exclusion category to the permissible limitation category in the same manner and for the same reasons as moving DME. The issues and analysis are nearly identical for home health care and DME. The rule as modified is needed, reasonable, and not substantially different from the rule as published in the *State Register*.

57. Subpart 4 lists the services that may be excluded from coverage. DME and home health care services were originally included in the list, but were moved to subpart 3 by the Department. The remaining items on the list are cosmetic services, dental services, nonemergency ambulance services, corrective devices for vision or hearing, experimental services, custodial care, injuries while on military service that are otherwise covered, services obtained outside the HMO and its referral process, certain inpatient expenses, and services subject to underwriting restrictions (commonly known as pre-existing conditions).

58. The Department reconsidered the exclusion for cosmetic services in light of Minn. Stat. § 62A.25, subd. 1. That statute expressly requires HMOs to cover reconstructive surgery. Subdivision 2 states:

> Subd. 2. Every policy, plan, certificate or contract to which this section applies shall provide benefits for reconstructive surgery when such service is incidental to or follows surgery resulting from injury, sickness or other diseases of the involved part or when such service is performed on a covered dependent child because of congenital disease or anomaly which

> has resulted in a functional defect as determined by the attending physician.[78]

59. The Department modified the exclusion for cosmetic services to exempt reconstructive surgery under Minn. Stat. 62A. The Judge notes that the statutory provision is identical in coverage to that mandated by Minn. Stat. § 62E.06, subd. 1(c)(2) for qualified plans. The modified language conforms the proposed rule to the statutory requirement and the current practices of HMOs. The rule is needed and reasonable. The modification does not constitute a substantial change.

60. The permissible exclusion for experimental services in item F of subpart 4 sets out the standards to be applied by an HMO in making its determination that a particular drug, device, treatment or procedure falls under this exclusion. As proposed by the Department, a preponderance of the evidence standard must be used to determine if a questioned drug, device, treatment or procedure is experimental or not.

61. The preponderance of the evidence standard was criticized by the Council as a "legal standard used in civil actions and is inappropriate for use in determinations regarding coverage of . . . interventions."[79] The Council proposed that "sufficient evidence" be used as the standard.[80] Perhaps recognizing that the term "sufficient evidence" is inherently subjective, the Council described the term as follows:

> Evidence is considered to be sufficient to draw conclusions if it is peer reviewed, is well controlled, directly or indirectly relates the intervention to health outcomes, and is reproducible both within and outside of research settings.[81]

Standing alone, the "sufficient evidence" standard proposed by the Council is too vague. The clarifying description supplied by the Council is itself ambiguous. The standard of "reproducible both within and outside of research settings" does not indicate whether the science must be clear enough to allow reproduction of result or whether the introduction of the item in controlled studies must be performed and the results already assessed. The difference between the two interpretations is considerable. In a prehearing comment, Kurt L. Malmgren, Vice President of the Pharmaceutical Research and Manufacturers of America (PhRMA), pointed out that the FDA approval process leads to “extensive clinical studies.”[82] Studies that are capable of reproduction would allow an item to be introduced to HMO enrollees upon completion of laboratory research and appropriate regulatory approval. As discussed below, the Department's proposed standard would require any studies relied upon to meet the "capable of reproduction" standard.

62. The level of proof of medical outcome proposed by the Council would require that extensive clinical studies already be performed before the "experimental" label would be removed.[83] If the outside studies must be already performed, the HMO

enrollee population would be denied access to the item for however long such outside studies would take to perform. PhRMA suggested that such studies “can take years.”[84] With the large population of HMO enrollees, the lack of outside studies can be a self-reinforcing reason to deny treatment. The very people who would participate in such clinical studies to confirm the laboratory findings (and thereby confirm that the approach is not "experimental") would be the people denied access to the treatment as being "experimental." The Department has shown the "preponderance of the evidence" standard to be needed and reasonable.

63. The Council maintained that the "reliable" evidence standard be replaced with "scientific" evidence. MDLC urged retention of the "reliable" evidence standard because of the small numbers of persons with disabilities significantly affects the ability of researchers to conduct large-scale scientific studies.[85] The proposed use of standardized written protocols was criticized by the Council as irrelevant to the question of whether an item is experimental or not. The Department accepted the comment and deleted the protocol evidence category. As finally proposed, the evidence to be relied upon by the HMO in making the determination regarding the experimental nature of that procedure, treatment, item, or drug is: a) any final government approval, b) consensus opinions or recommendations from the relevant literature, and c) consensus opinions of providers in the applicable area of medicine. The Council asserts that reliability is an insufficient standard because it only means that results are reproducible. As used by the Department in this rule, reliability relates to the credibility of the information sources and the particulars of any experiment done by any individual researcher. The scientific work is done by the entities relied upon for evidence regarding the nature of the procedure, treatment, item, or drug. To the extent that an HMO is aware of unscientific practices underlying a recommendation, the HMO can weigh the impact of such practices in determining whether a source of information is reliable. The qualification that the evidence used in the HMO's determination be reliable is both needed and reasonable. The deletion of the protocol evidence category is not a substantial change.

Proposed Rule 4685.1010 - Availability and Accessibility.

64. HMO service structure complexity was noted by the Department as a reason to amend these rules. When an enrollee requires services beyond the basic services immediately available, HMOs commonly use a system of referrals to ensure services are only being accessed where necessary to aid an enrollee's condition. Subpart 2 of proposed rule 4685.1010 requires HMOs to maintain services to meet the projected needs of enrollees. In response to a suggestion from the MMA, the Department added the requirement that HMOs coordinate with participating providers in developing the referral standards and assessing the system's capacity.[86] This portion of the rule is needed and reasonable. The new language is not substantially different from the rule as published in the *State Register*.

65. An obligation for referral procedures to be set out for enrollees is contained in item J of subpart 2. As originally proposed, the item required description of the circumstances when a referral is needed, how to make a request for referral, how to request a standing referral, how to determine if the referred service is covered, and how

to appeal a referral determination. The Department deleted the requirement on determining coverage of the referred service. This deletion addressed a concern of the Council regarding a potential conflict with a statute.[87]

66. The Council suggested adding language to state that "receipt of a referral does not guarantee coverage."[88] The Department expressly refused to make such a change, suggesting that such language can confuse enrollees as to the extent services are covered.[89] The Department asserted "that a referral, once issued, is a guarantee of coverage and may be relied upon."[90] The referral procedure language is needed and reasonable, as modified to delete the coverage determination language. The new language is not substantially different from the rule as published in the State Register.

67. MGCDD and MDLC suggested that the reference to "standing referral" in the rule should be defined.[91] The Department noted that the standing referral language comes from Minn. Stat. § 62Q.58.[92] The Department declined to suggest any language for a definition of standing referral and maintained that the issue was best addressed through legislation.[93] In the interim, there is no critical problem identified in the lack of a definition for the term in these rules. The rule is needed and reasonable without a definition of standing referral.

Proposed Rule 4685.1110 - Program.

68. The complaint procedure for enrollees dissatisfied with the service obtained from HMOs is contained in proposed rule 4685.1110. The proposed rule would require HMOs to conduct evaluations of all complaints received from enrollees, even if those complaints are filed with participating providers. The rule also requires a tracking system to permit evaluation of complaint resolution and identification of general trends. MMA expressed concern that HMOs would conduct complaint investigations at the provider level and thereby interfere with patient care.[94] The Council urged that the evaluation requirement be restricted to complaints against the HMO and not include providers.[95] The Council also suggested restricting the complaints covered by the rule to complaints relating to "quality of care".[96] MDLC supported the proposed rule language as addressing recurring problems in resolving complaints.[97] The Department restated that the rule was intended to track enrollee complaints arising from any level or type of service.[98] Subpart 9 is needed and reasonable as proposed.

69. Subpart 11 requires HMOs to maintain policies and procedures for selecting providers. MMA expressed concern that the standards for provider qualifications and selection in subpart 11 constitute a potential "barrier to the entry to practice of the healthcare professions beyond the current licensure requirements in state law."[99] MMA suggested that "policy" be deleted as a way to match the credentialling process with accepted community standards.[100] The Council objected to merely relying upon community standards for provider qualifications.[101] The Council suggested that "at a minimum" be added to clarify that HMOs had the discretion to set their own standards. The Department indicated that it intended that HMOs be able to select the "best available providers."[102] To ensure that the rule was clear on this point, the Department accepted the Council's suggestion and added "at a minimum" to the credential

provision. There is no evidence in the record to support a requirement that HMOs accept as a provider anyone with minimal credentials. The Department's modification clarifies the discretion of the HMOs to impose higher standards for providers. The subpart is needed and reasonable as modified. The new language is not substantially different from the rule as published in the *State Register*.

Proposed Rule 4685.1900 - Records of Complaints.

70. As part of the effort to improve the handling and tracking of enrollee complaints, the Department proposed modifying the existing provisions of Minn. Rule 4685.1900 setting the standards for recordkeeping regarding complaints. The Department responded to a commentator's suggestion and withdrew a suggested change in subpart 1. In subpart 2, the Department modified its proposed language to clarify that the documentation maintained on complaints must be retrievable. The modification is consistent with the existing practices of HMOs.[103] The Department also qualified the requirement note the complainant's telephone number to those times when the number is provided to the HMO.[104] The proposed rule is needed and reasonable, as modified. The new language is not substantially different from the rule as published in the *State Register*.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Department of Health ("Department") gave proper notice of this rulemaking hearing.

2. The Department has substantially fulfilled the procedural requirements of Minn. Stat. §§ 14.14, subds. 1, 1a and 14.14, subd. 2, and all other procedural requirements of law or rule so as to allow it to adopt the proposed rules.

3. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3 and 14.50 (i) and (ii).

4. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii), except as noted at Findings 40 and 45.

5. The additions and amendments to the proposed rules which were suggested by the Department after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, and Minn. Rule 1400.1000, subp. 1 and 1400.1100.

6. The Administrative Law Judge has suggested action to correct the defects cited in Conclusion 4 as noted at Findings 40 and 45.

7. Due to Conclusion 4, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3.

8. Any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

9. A Finding or Conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in the record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted except where otherwise noted above.

Dated this 21st day of September, 1998.

/s/

STEVE M. MIHALCHICK
Administrative Law Judge

Reported: Tape Recorded; No Transcript.

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[1] Exhibit 1H.
[2] Exhibit 1G.
[3] Exhibit 1E.
[4] SONAR, at 3; Exhibit L, at 2.
[5] *Id*. at 2
[6] SONAR at 6.
[7] SONAR, at 5-6.
[8] SONAR, at 6.
[9] SONAR, at 7.
[10] *Id*.
[11] SONAR, at 7-8.
[12] Laws of Minnesota 1997, Chap. 303, Sec. 1 (codified as Minn. Stat. § 14.002).
[13] SONAR, at 8.
[14] *Id*.
[15] *Id*.
[16] Minn. Stat. § 14.14, subd. 2, and Minn. Rule 1400.2100.
[17] Manufactured Housing Institute v. Pettersen, 347 N.W.2d 238, 244 (Minn. 1984); Mammenga v. Department of Human Services, 442 N.W.2d 786 (Minn. 1989).
[18] In re Hanson, 275 N.W.2d 790 (Minn. 1978); Hurley v. Chaffee, 231 Minn. 362, 367, 43 N.W.2d 281, 284 (1950).

[19] Greenhill v. Bailey, 519 F.2d 5, 10 (8th Cir. 1975).

[20] Mammenga v. Department of Human Services, 442 N.W.2d 786, 789-90 (Minn. 1989); Broen Memorial Home v. Minnesota Department of Human Services, 364 N.W.2d 436, 444 (Minn. Ct. App. 1985).

[21] Manufactured Housing Institute, supra, 347 N.W.2d at 244.

[22] Federal Security Administrator v. Quaker Oats Company, 318 U.S. 2, 233 (1943).

[23] Minn. Rule 1400.2100.

[24] Minn. Stat. § 14.15, subd. 3.

[25] Minn. Stat. § 14.05, subd. 2

[26] Exhibits 16 and 4.

[27] Exhibit 4.

[28] Exhibit 12.

[29] Exhibit 18, at 14.

[30] *Id*.

[31] Exhibits 16, 11, and 5.

[32] Exhibit 6.

[33] Exhibit 26.

[34] *Id*.

[35] Exhibit 24, at 6.

[36] *Id*.

[37] Exhibit 1, I-26.

[38] Exhibit 7, at 9.

[39] Exhibit 24, at 8.

[40] SONAR, at 22.

[41] Laws of Minnesota 1995, Chap. 234, Art. 2, Sec. 29.

[42] SONAR, at 22-23.

[43] SONAR, at 17.

[44] SONAR, at 17.

[45] SONAR, at 35.

[46] Exhibit 10 Attachments.

[47] Exhibit 7.

[48] Exhibit 24, at 21.

[49] Exhibit 30, at 15.

[50] Exhibit 12.

[51] Exhibit 13.

[52] Proposed rule 4685.0700, subp. 3.A(2)(a).

[53] Exhibit 16, at 2, and Exhibit 22.

[54] Exhibit 23, at 2 (emphasis added).

[55] Exhibit 17, at 2, Exhibit 23, at 1, and Exhibit 1, I-54.

[56] Exhibit 25, at 25.

[57] Exhibit 30, at 15.

[58] Exhibit 24, at 26.

[59] Minn. Rule 4685.0700, subp. 3.A.

[60] Exhibit 1, I-1, I-3, I-7, I-9, I-10, I-11, I-14, I-15, I-16, I-17, I-18, I-19, I-22, 1-23 and I-24.

[61] Exhibit 1, L, at 8.

[62] Exhibit 7, at 3-5, and Exhibit 18, at 2.

[63] Exhibit 7, at 7.

[64] Exhibit 1, I-3.

[65] Minn. Stat. § 62E.06, subd. 1(b)(10).

[66] Minn. Stat. § 62E.06, subd. 4

[67] Exhibit 11.

[68] Exhibit 12, at 2.

[69] Exhibits 6 and 16.

[70] Exhibit 2, at 1.
[71] Exhibit 18, at 2.
[72] *Id*. at 3.
[73] *Id*. at 4 (emphasis added).
[74] Exhibit 24, at 15.
[75] Minn. Stat. § 14.05, subd. 2.
[76] Minn. Stat. § 14.05, subd. 2.
[77] *See* Exhibit 1, I-53.
[78] Minn. Stat. § 62A.25, subd. 2.
[79] Exhibit 18, at 12.
[80] *Id*.
[81] Exhibit 18, at 13.
[82] Exhibit 1, I-12.
[83] Exhibit 28, at 3.
[84] *Id*.
[85] Exhibit 16, at 5.
[86] Exhibit 1, L at 10.
[87] Exhibit 30, at 19.
[88] Exhibit 18, at 18.
[89] Exhibit 30, at 20.
[90] *Id*., Exhibit 24, at 33.
[91] Exhibit 12 and Exhibit 1, I-23, at 3.
[92] Exhibit 24, at 12.
[93] *Id*.
[94] Exhibit 17, at 3.
[95] Exhibit 1, I-26, at 10.
[96] *Id*.
[97] Exhibit 1, I-23, at 5.
[98] Exhibit 24, at 35-36.
[99] Exhibit 17, at 4.
[100] *Id*.
[101] Exhibit 1. I-26, at 11.
[102] Exhibit 24, at 39.
[103] Exhibit 24, at 41.
[104] *Id*.